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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,378	10/25/2000	John Jianhua Chen	S63.2-9503	2980
490	7590	07/03/2002	EXAMINER	
VIDAS, ARRETT & STEINKRAUS, P.A. 6109 BLUE CIRCLE DRIVE SUITE 2000 MINNETONKA, MN 55343-9185			HON, SOW FUN	
ART UNIT		PAPER NUMBER		
1772		DATE MAILED: 07/03/2002		/

Please find below and/or attached an Office communication concerning this application or proceeding.

MF/11

Office Action Summary	Application No.	Applicant(s)	
	09/696,378	CHEN ET AL.	
	Examiner	Art Unit	
	Sow-Fun Hon	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 June 2002.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 27-30 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-26 and 31-36 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 27-30 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 October 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>8</u> .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,6,7</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: The status of the parent application US 09/426,384 should be revised to “abandoned”, as confirmed in the telephone interview on 06/26/02 with Lisa Ryan-Lindquist.

Appropriate correction is required.

Drawings

2. The objections by the Draftsperson under 37 CFR 1.84 or 1.152 to the drawings submitted in parent application US 09/426,384 hold for the same drawings submitted in the present application. Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the abandonment of the application.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-26, 31-36, drawn to an article, classified in class 428, subclass 35.7.
- II. Claims 27-30, drawn to a method, classified in class 264, subclass 108.

The inventions are distinct, each from the other because of the following reasons:

4. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polymer balloon can be made using interface reactive two-component injection molding which mixes and orients the fibril component before extrusion.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Lisa Ryan-Lindquist on 06/18/02, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-26, 31-36. Affirmation of this election must be made by applicant in replying to this Office action. Claims 27-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-26, 31-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. It is unclear what the term “substantially diagonally to the longitudinal axis” means. Does it mean that it can be any angle away from 0 degrees to the axis? In which case, it is unclear what the term “substantially parallel” means unless it is at 0 degrees to the axis.
- b. It is unclear what the difference is between the terms “rigid-rod” and “semi-rigid rod” is.
- c. It is unclear what the term “semi-compliant” means with respect to a standard.
- d. It is unclear what the limitation “orientation of the microfibers relative to the longitudinal axis of the balloon changes through the balloon material in a direction transverse to said longitudinal axis” means. Does it mean that the microfibers wind helically around the central longitudinal axis of the balloon?
- e. It is unclear what the term “cores” mean. Are they the cores of the fibril components?
- f. It is unclear what the claim limitation “operatively adhering” means. Does it mean that the fiber surface adheres to the matrix? If so, then applicant is reminded that values are needed to define the level of adhesion of the fiber surface to the matrix.
- g. It is unclear how the matrix component can be 10 to 12 microns in diameter, unless it is actually the fibril component.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1-8, 12-14, 19-26, 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgensen (US 5,647,848) in view of Zdrahala (US 5,156,785).

Jorgensen has a dilation balloon for securing to (the distal end of) a catheter, wherein the balloon is formed of an elastomeric skin with a constraining structure embedded in the elastomeric skin. The constraining structure is formed of liquid crystal polymer fibers with a diameter (thickness) of less than 15 microns (column 3, lines 25-50). One of ordinary skill in the art would have chosen fibers with a specific elongation to break of 50-500 % for a specific constrained inflation of the catheter balloon. Jorgensen fails to teach the claimed longitudinal orientation of the liquid crystal polymer fibers.

Zdrahala has extruded catheters with improved longitudinal stiffness (abstract). Zdrahala teaches that the orientation of the liquid crystal polymer at the distal tube end is substantially longitudinal, to provide a catheter section of relatively low rotational stiffness and relatively high longitudinal stiffness which is desired for a distal catheter tip to facilitate advancement through small arteries or veins (column 2, lines 42-52). A suitable liquid crystal polymer is a terpolymer of hydroxybenzoic acid, ethylene glycol and terephthalic acid (column 3, lines 55-60). It is generally preferred for the composition to contain from 5 to 35 weight percent of the liquid crystal polymer (column 5, lines 16-30). The matrix may be composed of polyurethanes and

thermoplastic elastomers (column 5, lines 30-35) which are either compliant or semi-compliant and are taught to be elastomers such as polyester-polyether block copolymers (HYTREL) and polyamide-polyester (PEBAX) block copolymers (column 4, lines 15-30) which have melting points between 150 °C and 230 °C. Zdrahala teaches that the tube may be extruded with no relative rotation between orifice and mandrel, but with stretching imposed by orienting apparatus, with the result that the fibrils of such tubing are generally parallel to the tubing axis where such a structure tends to have relatively high longitudinal stiffness (column 8, lines 1-5) which means that the longitudinal elongation of the catheter section would be minimal, and precludes longitudinal expansion of 5 % beyond the original preinflation state. Other additives such as compatibilizers (surfactants) are taught (column 5, lines 16-30). Orientation of the liquid crystal fibrils in a helical direction is also taught (column 5, lines 50-55).

Because Zdrahala teaches that the orientation of the liquid crystal polymer at the distal tube end is substantially longitudinal, to provide a catheter section of relatively low rotational stiffness and relatively high longitudinal stiffness desired for a distal catheter tip to facilitate advancement through small arteries or veins, it would have been obvious to one of ordinary skill in the art to have used the teachings of Zdrahala in the invention of Jorgensen in order to obtain a balloon catheter with the desired longitudinal stiffness and constrained inflation.

12. Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over as applied to claims 1-8, 12-14, 19-26, 31-36 above, and further in view of Cozewith et al. (US 5,733,980).

Jorgensen has been discussed above, and fails to teach the use of a compatibilizer in the blend.

Zdrahala has been discussed above, and teaches that the liquid crystal polymer ingredient may be desirably semi-compatible with the particular structural plastic matrix (column 5, lines 35-40) and that the blended composition may include block copolymers such as copolyester elastomers and polyolefins as listed (column 4, lines 15-30) and the specific use of compatibilizers (surfactants) (column 5, lines 20-35). Zdrahala, however, fails to teach that any block copolymer in the blend is specifically a compatibilizer.

Cozewith et al. discloses that it is well known in the art to use block copolymers as compatibilizers for emulsifying polymer/polymer blends (column 1, lines 15-25) and that the block copolymer compatabilizer is composed of two or more polymer molecules of different chemical composition are covalently bonded in an end-to-end fashion (column 1, lines 15-35).

Because Cozewith et al. discloses that it is well known in the art to use block copolymers as compatibilizers for emulsifying polymer/polymer blends, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used a block copolymer taught by Zdrahala as a compatibilizer in the invention of Jorgensen, in order to obtain a balloon catheter with the desired compatibility between matrix and fiber and thus the desired constrained inflation and longitudinal stiffness.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claim 11 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,242,063 in view of Zdrhala. Zdrhala compensates for the deficiencies of US 6,242,063 by teaching and that the orientation of the liquid crystal polymer at the distal tube end is substantially longitudinal, to provide a catheter section of relatively low rotational stiffness and relatively high longitudinal stiffness which is desired for a distal catheter tip to facilitate advancement through small arteries or veins.

15. Claims 15-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,284,333 in view of Zdrhala. Zdrhala compensates for the deficiencies of US 6,242,063 by teaching and that the orientation of the liquid crystal polymer at the distal tube end is substantially longitudinal, to provide a catheter section of relatively low rotational stiffness and relatively high longitudinal

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stiffness which is desired for a distal catheter tip to facilitate advancement through small arteries or veins.

Any inquiry concerning this communication should be directed to Sow-Fun Hon whose telephone number is (703)308-3265. The examiner can normally be reached Monday to Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on (703)308-4251. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

8H
06/26/02


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

6/26/02